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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,691	06/26/2001	John Bondo Hansen	6034.200-US	1796

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/13/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/891,691

Applicant(s)

HANSEN ET AL.

Examin r

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears n the cover sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 19-24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on June 11, 2002 in Paper No. 8 wherein claim 2 has been amended and claims 28-36 are cancelled. Currently, claims 1-27 are pending in this application.

Election/Restrictions

Applicant's affirmation of the telephonic election with traverse of the invention of Group I, claims 1-27 and the invention of the species of claim 27, in Paper No. 8, submitted June 11, 2002 is acknowledged.

Claims 13-18 and 25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species. See the previous Office Action dated January 15, 2002.

The claims have been examined insofar as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "from about 10 kcal% fat" in claim 2 renders claim 2 indefinite. The expression "from 10 kcal% fat" is not understood in terms of the range of fat

percentage (from.....to.....). Therefore, the scope of claim is indefinite as to the fat-containing food encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 19-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US 5889002, WO 9726265, and WO 9903861) in view of Applicant's admission regarding the prior art (see pages 1-2), essentially for reasons of record stated in the Office Action dated January 15, 2002.

Applicant's remarks filed on June 11, 2002 in Paper No. 8 with respect to this rejection of claims 1-12, 19-24, and 26-27 made under 35 U.S.C. 103(a) of record stated in the Office Action dated January 15, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant asserts that the compounds disclosed by Nielsen et al. is very different from the compounds of the general formula I herein, but fails to point out specifically what is the difference. Applicant's assertion regarding the difference in compounds of the general formula I is not found persuasive since the compounds of Nielsen et al. (US

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5889002, WO 9726265, and WO 9903861) are clearly seen to be same as the instant compounds of the general formula I, covering the instant elected species. Applicant further asserts that the instant application also discloses that intracerebroventricular administration of the potassium channel openers minoxidil and pinacidil increase intake of food by mice (see page 4 in the Applicant's response). However, the instant claims are not limited to the intracerebroventricular administration of the potassium channel openers minoxidil and pinacidil in mice.

As discussed in the previous Office Action, the active compounds herein are not only known to be potassium channel openers, but also known to be useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease, diabetes and obesity, and decreasing weight gain according to Nielsen et al. Moreover, since the amount of fat-containing food to be consumed or fat intake is well known to be tightly associated with risk of obesity, hypertension, diabetes, and coronary heart disease according to the prior art, one of ordinary skill in the art would have reasonably expected that the active compounds of Nielsen would have beneficially therapeutical effect on reducing the consumption of fat-containing food, absent evidence to the contrary.

Furthermore, Nielsen's method inherently reduces the consumption of fat-containing food, as claimed herein since Nielsen's method steps are same as the instant method steps and that the range of effective amounts of active compounds therein to be administered is within the instant range. See *Ex parte Novitski*, 26 USPQ

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2d 1389. Thus, the instant claimed method is inherently present in the prior art. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Additionally, it is noted that Applicant admits herein that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake since Applicant employs an obese Zucker rat as the testing model for the instant claimed method. See page 23 lines 1-15 in the specification. Thus, Applicant clearly acknowledges that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake as discussed by the examiner above. Therefore, Applicant's own admission supports the examiner's position for the motivation for the instant invention.

Applicant's testing results in the specification at page 23 lines 1-15 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive since the results on the employment of the particular compound on obese rates show expected therapeutic effects as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Further, testing herein merely demonstrate a single particular compound within the broad genus of the instant claims. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the actives in the claimed method herein. See MPEP § 716.02(d).

Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
August 5, 2002


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